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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,064	11/14/2003	Edwin V. Oaks	38644-198794	9047

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VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,064	OAKS ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) *7-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-25 are pending.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 13-21, 23-25 are rejected under the judicially created doctrine of double patenting over claims 13-21 of U. S. Patent No. 6,245,892 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

3. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The methods are of the same, equivalent and/or identical scope based upon the same starting material, methods steps recited, reagents used in the methods and the products obtained or identified following the methods steps of each method.

4. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,245,892. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claims are directed to undenatured water extracted immunogenic compositions, and the instantly claimed invention compositions include the allowed species; the instantly claimed genus of compositions includes both denatured and undenatured compositions (instant claims 1-12) which may or may not be immunogenic, but comprise the same components as recited in the allowed claims. The allowed species anticipates the instantly claimed genus of compositions.

5. Claims 1-12, 23-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, and 9, respectively of U.S. Patent No. 6277379. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claims are directed to undenatured water extracted immunogenic vaccine compositions, and the instantly claimed genus of compositions include the allowed species; the instantly claimed genus of compositions includes both denatured and undenatured compositions (instant claims 1-12) which may or may not be immunogenic, but comprise the same components as recited in the allowed claims. The allowed species anticipates the instantly claimed genus of compositions and method of eliciting an antigen specific immune response.

6. Claim 22 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,680,374 Although the

conflicting claims are not identical, they are not patentably distinct from each other because the allowed species anticipate the instantly claim genus of antibodies.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. The antibody of claim 22 is not isolated and purified and therefore reads on a product of nature; the claimed invention is directed to non-statutory subject matter.

Claim Objections

9. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 depends from itself and is therefore not further limiting of the claim.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2-6, 7-8, 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 depends from itself and is therefore not further limiting and unclear.

Claim 8 depends from claim 7 which is unclear, and is therefore unclear as well.

Claims 2-6 and 9-12 recite the indefinite article "A" and depend from a prior claim. The claims should specifically refer back to the prior claim or claims and should recite ----The-----.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1,2,3,6, 18-19, 20-21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Oaks et al (March 1996).

(Instant claims 1-3, 6) Oaks et al (1996) disclose a water extracted invasion antigen preparation that comprises IpaB, IpaC, IpaD, VirG and LPS (see page 242, col. 1, middle of column , Shigella species recited are Shigella flexneri or sonnei (see abstract)).

(Instant claims 18-19, 20-21) Oaks et al disclose a method of detecting gram negative bacterial infection, the method comprising the step of :

contacting a sample with a the solid surface to which is attached Invaplex from bacteria (see page 242, Western blot IpaB; ELISA, LPS and IpaB, IpaC, IpaD and VirG antigens immobilized) to detect Shigella or E.coli; also see Table 1, page 243;page 243,col. 2,paragraph 1),

detecting the presence or absence of a complex, the sample being from an animal (monkeys, see title; "humans", page 242, col. 2, bottom of first paragraph; see page 244, col. 2, paragraph 2, "healthy, adult US citizens").

(Instant claim 22) Oaks et al disclose an antibody composition directed to IpaB, IpaC and IpaD (see page 244, col. 1, paragraphs 2 and 4). As well as disclose "(Ipa) proteins (IpaB, IpaC, IpaD, VirG (IcsA) and lipopolysaccharide (LPS) elicit substantial antibody response in the serum as well as in secretions after infection (see page 242, col. 1, top of paragraph).

The reference anticipates the instantly claimed invention.

14. Claims 1-6, 9-12, 22, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexander et al (1996).

Alexander et al disclose the instantly claimed invention directed to:

(Instant claims 1-6, 9-12) a composition that comprises an isolated hybrid strain that expresses IpaA, IpaB, IpaC, IpaD, LPS and VirG, specifically a E.coli/Shigella flexneri hybrid strain that expresses the Shigella flexneri plasmid invasion proteins (strain 7921 see Figure 1, and Figure 4) and

(Instant claim 22) antibodies that bind to Invaplex or any portion thereof (IpaB and IpaC monoclonal antibodies; anti-LPS antibodies).

Alexander et al also discloses a method of eliciting an antigen specific immune response in a subject, the method comprising the step of :

administering orally (ocularly is an oral route of administration) an Invaplex from a gram negative bacteria (shigella) along with said antigen (E.coli), wherein the Invaplex was encoded and expressed by Shigella flexneri virulence invasion plasmid (IpaA, IpaB, IpaC, IpaD and LPS)(see Figure 5). The antigen being an E.coli antigen, a bacterial antigen, which was administered to a mammal for induction of a humoral immune response (see page 1058, Figure

5) that was protective, wherein an immune response to the encoded and expressed Invaplex antigen (see Table 1, page 1056, col. 2, paragraphs 2-3) was also elicited. Both Ipa, IpaC were expressed by the vaccine vector and reacted with monoclonal antibodies directed to each proteins). Antibodies (IgG) to Shigella flexneri 2a LPS were also elicited (see page 1058, col. 1, last paragraph; col. 2, paragraph 2 "sIgA" was induced)

The reference anticipates the instantly claimed invention.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Simonet et al (1996), Pace et al (US Pat. 6,083,683); Venkatesan et al (1988), Swiss Prot accession number Q5112(VirG), Accession number P18010(IpaA), Accession number Q03945 (IpaB), Accession Number Q03946 (IpaC), Accession Number Qo3947 (IpaD), Thirumalai et al (1997)Nhieu etal (1997), Barzu et al (1996), Turbyfill et al (1995), Mikhail et al (1996) are cited as being duplicative of the applied references, or to show the state of the art with respect to invasin proteins for Shigella.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
September 15, 2004

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600